Preparing for the inevitable

Global Vaccine and Immunization Research Forum

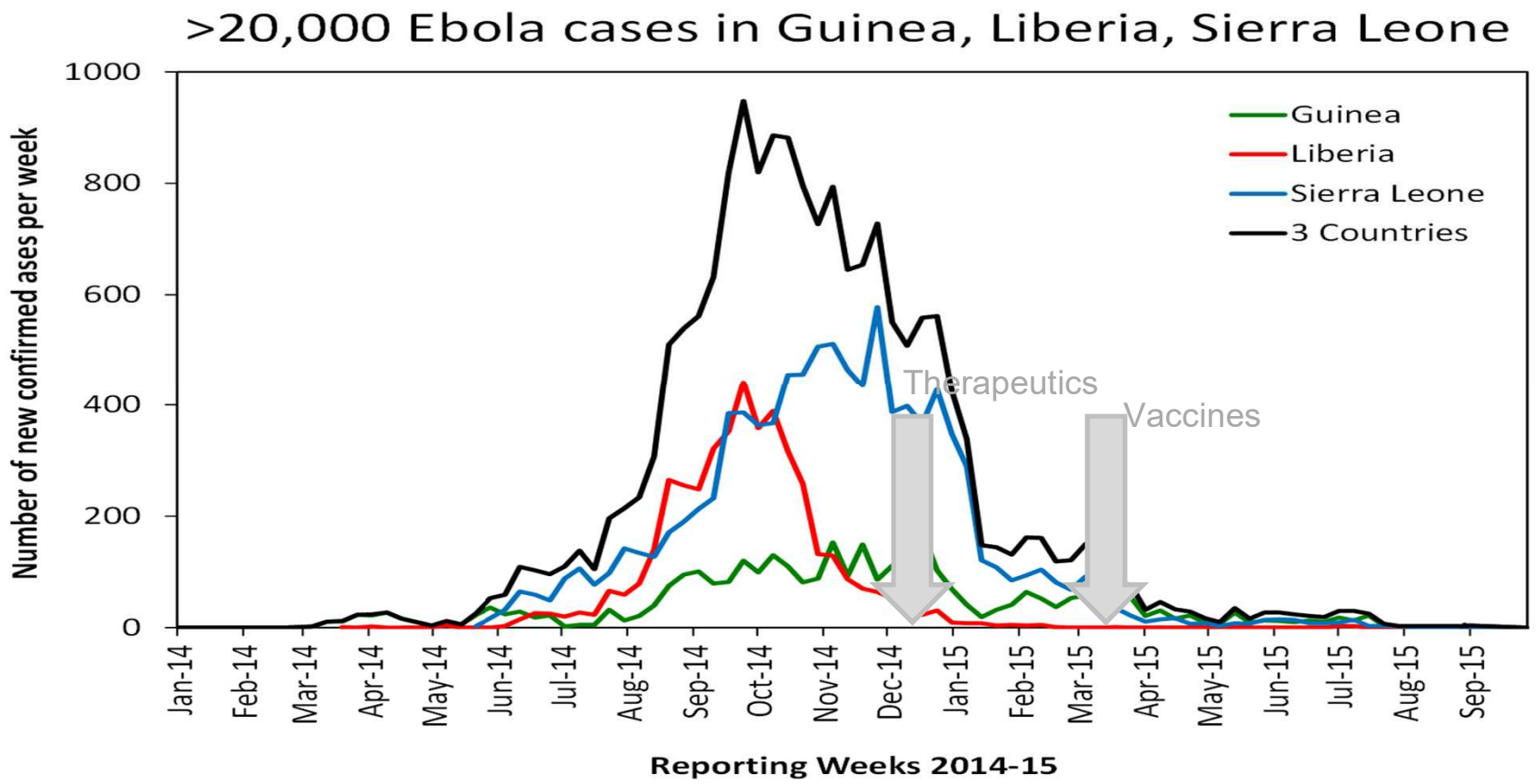
15 – 17 March 2016
Johannesburg, South Africa

World Health Organization

Preparing for the inevitable: the WHO R&D Blueprint

With more frequent travel, globalized trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming as inevitable as they remain unpredictable

Problem statement



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Overall Ebola R&D Achievements

1) Clinical trials underway by December 2014 in the affected countries, each of which were "clinical trial naïve" prior to the epidemic

2) Efficacy results available on at least:

(a) 1 vaccine

(b) 6 diagnostics

(c) 5 therapeutics

Pending questions for Ebola R&D

- Survivors
  - –future support of survivors; study and treatment of sequelae
- Future public health use of investigational products
  - –**Vaccines; e.g contacts of survivors; front line staff; disease flare-ups**
  - –CP; anti-Ebola antibodies vs. outcome
- Future research studies
  - –For example in non human primates
- Health systems capacity strengthening
  - –Ebola has illustrated need across West Africa; **how to build access to systems and products**

68th World Health Assembly, 2015

*"….welcomed the development of a **Blueprint** — in **c**onsultation with Member States and relevant stakeholders— **f**or **accelerating research and development** in epidemics where there are **no, or insufficient, preventive, and curative solutions**, taking into account other relevant work-streams within WHO"*

G7 Health Ministers, G7 2015

*"…**continued financing, collaboration and coordination** ….through initiatives such as **WHO blueprint for R&D preparedness** and the Global Research Collaboration for Infectious Disease Preparedness **(GloPID-R)."***

Supporting pandemic preparedness

- U.S. National Academy of Medicine calls for $4.5Bn for pandemic preparedness
  - $1Bn of which is for Therapeutics, Diagnostics and Vaccine development
  - WHO to serve as secretary
- “In preparation for a future public health emergency, the World Health Organization (WHO) should consider creating a permanent capability within the organization to coordinate accelerated regulatory review” – Ebola Vaccine Team B

Two key and complementary objectives for the Blueprint

- to develop (and implement) a roadmap for R&D preparedness for known priority pathogens, and
- to enable roll-out of an emergency R&D response as early and as efficiently as possible

How is the Blueprint being developed?

Driven by scientific knowledge

An inclusive process with a clear mandate and defined milestones

Building on the efforts of others

A collaborative effort with Member States and other relevant stakeholders

What concrete benefits are expected from the implementation of the R&D Blueprint?

Better R&D preparedness for diseases which might lead to epidemics

- Identification of the 5 (to 10) top priority diseases
- Mapping of pipelines for medical technologies
- List of optimal attributes for medical technologies (Target Product Profiles)
- Diagnostic tools to identify emerging outbreaks due to top priority diseases
- Innovative approaches to leverage industry's expertise (through R&D and production platforms)
- Mechanisms to improve global coordination
- A portfolio of promising experimental medical technologies (e.g. treatments and vaccines) for the top priority diseases, with results available from Phase 1 safety trials in man

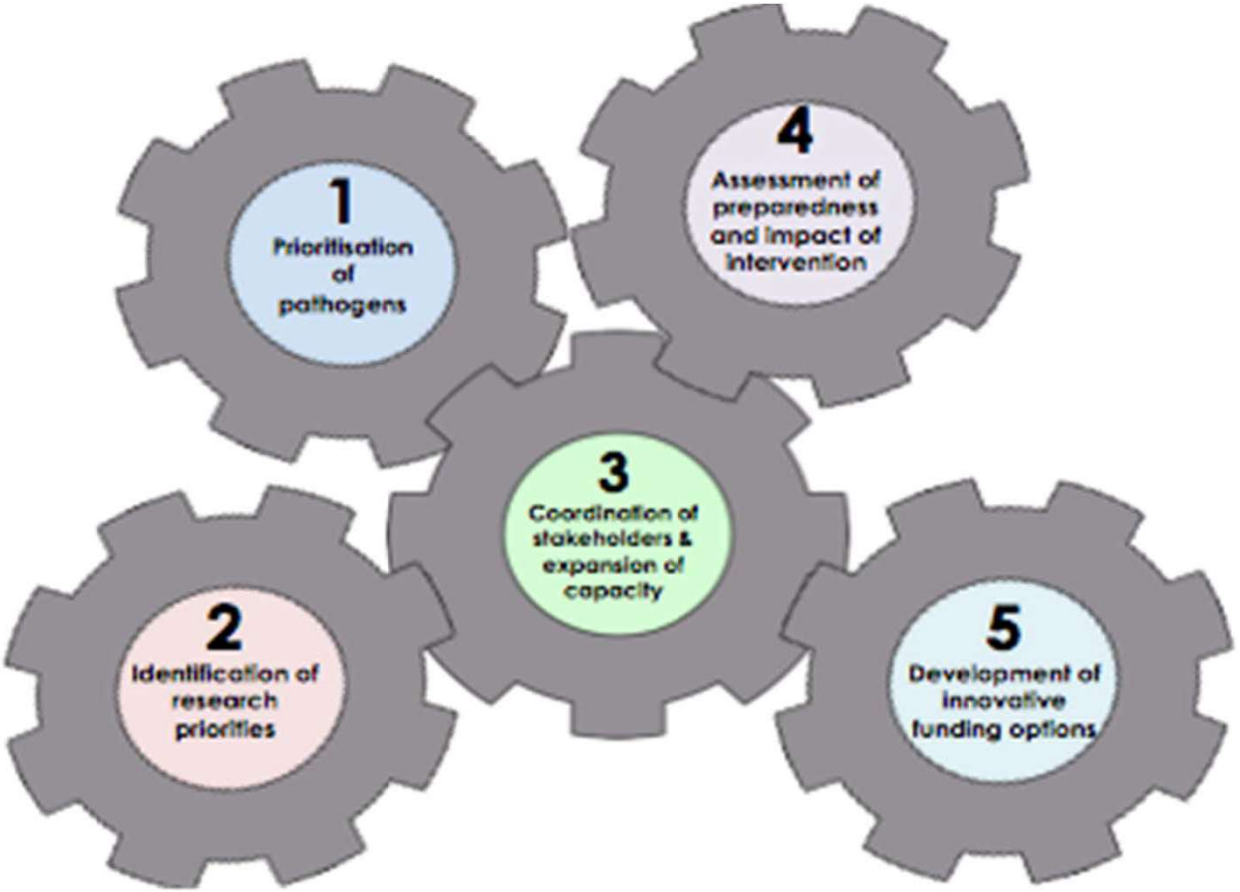
What concrete benefits are expected from the implementation of the R&D Blueprint?

Better readiness to promptly conduct R&D during an emergency

- Mechanisms to improve global coordination
- Identification of pathways to produce, procure, deliver and use priority health technologies during an emergency
- Better and stronger ethical and regulatory capacity in low- and middle-income countries
- Mapped and strengthened networks of clinical trial centres and experts – both in the North and the South
- A toolbox of generic protocols and agreements
- Solutions for liability and indemnification challenges for manufacturers
- Options to take into consideration the Nagoya Protocol obligations with a view to facilitate sharing of samples and accelerating detection of infectious threats

Five work-streams

designed to identify key actions required to achieve the objectives



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First Blueprint deliverables

Prioritization of key Pathogens

The initial list of disease priorities needing urgent R&D attention comprises: Crimean Congo haemorrhagic fever, Ebola virus disease and Marburg, Lassa fever, MERS and SARS coronavirus diseases, Nipah and Rift Valley fever. Chikungunya, severe fever with thrombocytopaenia syndrome, and Zika designated as "serious". The list will be reviewed annually or when new diseases emerge.

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Platform Technologies Consultation

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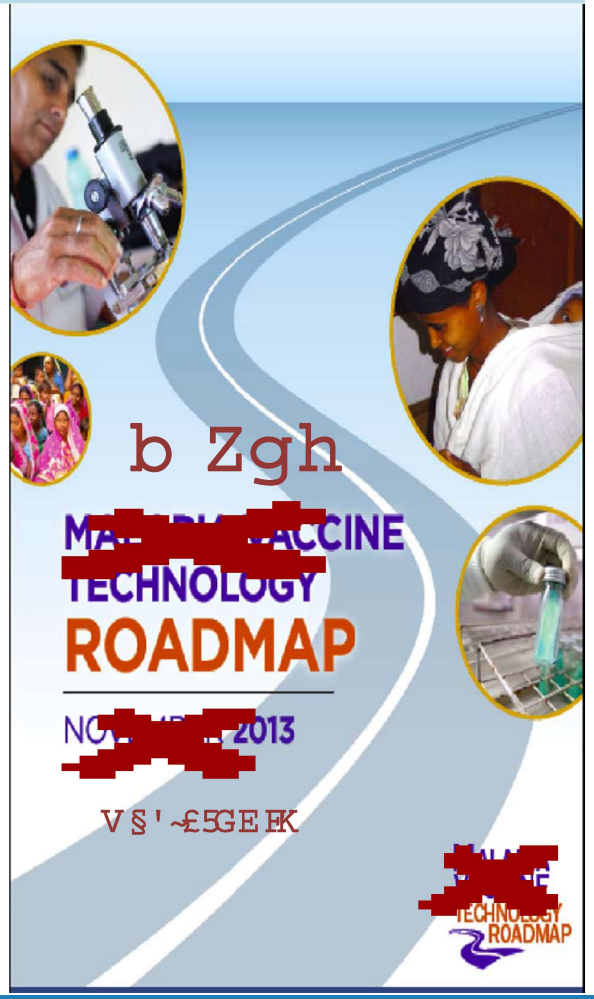
Development of R&D Roadmaps for priority pathogens

Roadmaps as a Vehicle for Addressing Large-Scale Public Health Challenges



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Governance and coordination

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Data Sharing
ICJME Recommendations, 2015

<<New paragraph>>
In the event of a public health emergency (as defined by public health officials), information with immediate implications for public health should be disseminated without concern that this will preclude subsequent consideration for publication in a journal.

concern. See Section IV.g.i. for referencing retracted articles.

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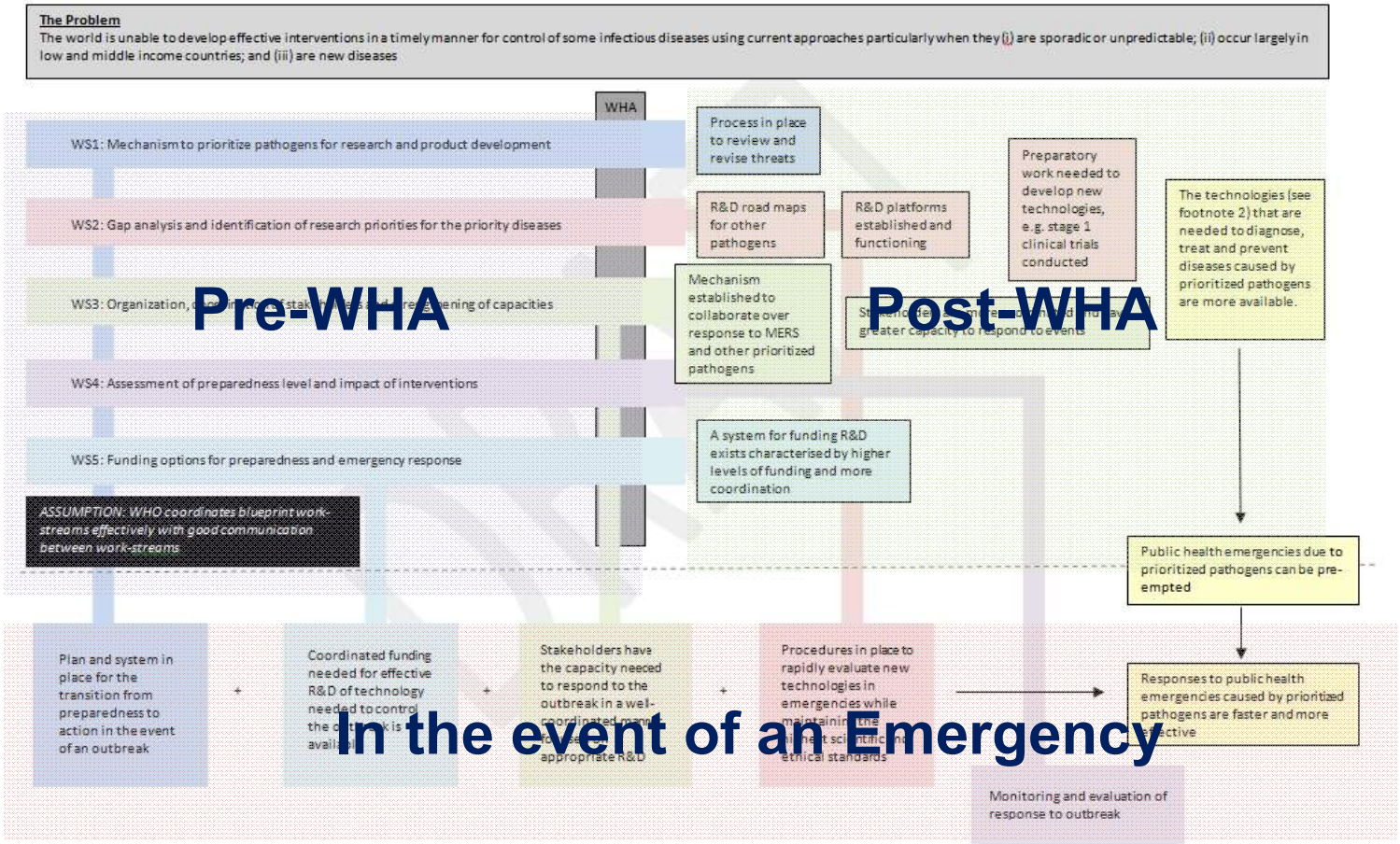
submit the same manuscript, in

abstract or poster displayed at a scientific meeting. It also does not prevent journals from considering a paper that has been presented at a scientific meeting but was not published in full, or that is being considered for publication in proceedings or similar format. Press reports of scheduled meetings are not usually regarded as breaches of this rule, but they may be if additional data tables or figures enrich such reports. Authors should also consider how dissemination of their findings outside of scientific presentations at meetings may diminish the priority journal editors assign to their work. ~~An exception to this principle may occur when information that has immediate implications for public health needs to be disseminated, but when possible, early distribution of findings before publication should be discussed with and agreed upon by the editor in advance.~~

Sharing with public media, government agencies, or manufacturers the scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances; reportable diseases; or

Monitoring and evaluation Framework



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Oslo Consultation on Financing Options

Outcome document
Financing of R&D Preparedness and Response to Epidemic Emergencies
October 29-30, 2015
Oslo, Norway

Norwegian Institute of Public Health

Background

This Outcome document summarizes discussions that took place during the Oslo consultation on *Financing of R&D Preparedness and Response to Epidemic Emergencies* (October 29-30, 2015). It reflects views expressed and the discussion that took place, but does not necessarily reflect all interventions. Names of representatives of countries and organizations participating in the Oslo consultation on Financing can be found on the webpage of the Norwegian Institute of Public Health. Stakeholders represented included government, industry, NGOs and academia as well as charitable foundations

Future shape of R&D Blueprint World Health Assembly 2016

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EXECUTIVE BOARD
138th session
Provisional agenda item 9.1

EB138/28
20 November 2015

Options for strengthening information-sharing on diagnostic, preventive and therapeutic products and for enhancing WHO's capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers

Report by the Secretariat

BACKGROUND

1. In resolution EBSS3.R1, adopted in January 2015 by the Executive Board at its special session on the Ebola emergency,[1] the Director-General was requested to provide to the Executive Board at its

Zika R&D priorities
(WHO consultation, 4-6 March 2016)

- Multiplex diagnostics (Zika, Dengue, Chikungunya)
- Innovative vector control measures
- Inactivated Zika vaccines for women of child-bearing age

<u>Current Zika vaccine pipeline</u>

- currently 18 research projects on vaccines
  - inactivated; live attenuated; VLP; DNA

WHO areas of work on Zika vaccines

- Target product profile for emergency use
- Target product profile for routine use
- Continued landscaping of vaccine development
- Facilitate partnering for vaccine development
- Targeted action to overcome bottlenecks